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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/960,706  | 09/24/2001  | William E. Munger    | 044921-5029-01      | 4547             |
| 9629  | 7590        | 08/11/2006           | EXAMINER            |                  |
| MORGAN LEWIS & BOCKIUS LLP<br>1111 PENNSYLVANIA AVENUE NW<br>WASHINGTON, DC 20004 |             |                      | MORAN, MARJORIE A   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1631                |                  |

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/960,706

Applicant(s)

MUNGER ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 57-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 7. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57-69 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Applicant's arguments filed 5/22/06 have been fully considered but they are not persuasive. In response to the argument that the specification discloses an HP Gene Array Scanner which is used as an "interface" to enter information from an array scan into a computer, it is noted that transfer of data from one computer/machine to another does not necessarily require a *user* interface. A "user" is generally understood by those of skill in the art to be one performing a method; i.e. a person. A "user" is not otherwise defined by the specification, therefore the term has been interpreted to have the "normal

and customary" meaning. It is noted that because a "user" is interpreted to be a person, the "user interface" recited in the claims has been interpreted to be a physical element of the computer system, thereby rendering the system statutory. If applicant intends a "user interface" to be other than one used by a person; e.g. an interface between computer "components," then the claims do not recite any physical or "hardware" limitations. Applicant is advised that a computer system encompassing only a database and software is not necessarily a physical article of manufacture, and may not be statutory. However, applicant has not specifically defined nor argued that a "user" is intended to be something other than a person, but merely argues that an "interface" between two machines or computer components is supportive of the claimed "user interface." As set forth above, this argument is not persuasive as an "interface" or connection between two machines or computer components is not support for a *user* interface; specifically one wherein a *user* may enter data. Applicant does not point to specific support in the originally filed disclosure for a "user interface" and none is apparent, as set forth in the previous office action, therefore the examiner maintains that a "user interface" is new matter.

With regard to software for comparing statistical values from a first data set to a *database* to thereby generate a second experimental data set, applicant points to pages 22-23 for support. In response, it is noted that page 23, lines 11-20 does indeed disclose comparing statistical information of differentially expressed genes in "normal" patients to those from a "symptoms disease" groups. This is interpreted to correlate to part (a) of claim 57. It is recognized that the data thus obtained according to the

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method of pages 22-23 may be used to CREATE the database recited in part (b) of instant claim 57, but page 23 does not, in fact, disclose making or using any such database. Page 23 does not disclose comparing the statistical data derived from the normal and disease genes to an already existing database such as recited in claim 57. Nowhere does the specification disclose software for comparing any sort of data to a database *in order to generate a second data set which is indicative of the presence or absence of BPH*. Original claim 32 recited a computer system comprising a database, and original claim 39 recited using the database for comparison purposes. However, none of the original claims recited comprising statistical information on experimental gene expression to a database *in order to generate a second data set indicative of the presence or absence of disease*. With regard to applicant's reference to the "entirety" of the Affymetrix GeneChip Expression Analysis Manual, it is noted that neither the entire manual, or just those portions of it deemed to be relevant by applicant have been filed and properly cited in an IDS, nor presented as evidence in support of applicant's position, therefore the examiner can not assess the whether the Manual does, in fact, teach the newly recited limitation. Further, applicant is reminded that incorporation by reference of nonpatent literature is improper where the incorporated material is "essential" to patentability, as set forth under 37 CFR 1.57(c). As applicant appears to be relying on the Manual (or at least some portion thereof) to comply with the written description requirement under 35 USC 112, then the Manual appears to be both material to and essential to patentability under 37 CFR 1.97 and 1.98, and applicant is advised that the specification may not be in compliance with 37 CFR 1.57 (c)(1).

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However, as it is unclear whether the Manual is, in fact, being relied upon to provide a "full and complete" disclosure of the claimed subject matter, no objection to the specification is made at this time. In addition, until such time as evidence is presented to show that the material incorporated by reference does, in fact, provide support for the newly recited claimed limitations, the examiner maintains that part (c) of claim 37 recites new matter.

With regard to ranges, applicant is reminded that a new range must have specific support in the same manner that a new species or subgenus must have support, in the originally filed disclosure. Disclosure of a larger range or genus is NOT necessarily supportive of the narrower range or species, as set forth in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), therefore applicant's arguments with regard to the very large range represented by the entirety of the data in the Tables is not persuasive. Applicant's attention is directed to MPEP 2163.05, in particular, section III for further support for the examiner's position.

For all the reasons set forth above and previously set forth, the rejection is maintained.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
8/4/06